

**Summary of
Complaint Against the EPA**

- I. The EPA Has Adjusted Science to Fit Predetermined Policy Objectives.**
- A. An independent expert review panel, convened by the EPA, found that the Agency improperly ignores science in its early decision making and is perceived as "adjusting" science to fit EPA's predetermined policies.
- B. This criticism of EPA's practice, of first making policy and then adjusting science to fit that policy, squarely applies to EPA's handling of ETS issues.
- II. EPA's Preparation and Issuance of the ETS Risk Assessment Violated the Terms and Limitations of the Radon Act.**
- A. The Radon Act, which is the sole source of EPA's authority over indoor air quality and ETS, prohibits EPA from pursuing regulatory action, as has been undertaken with respect to ETS.
- B. The Radon Act expressly states that it grants EPA no authority to regulate indoor air quality, nor does it authorize EPA to take any action, other than research, in preparation for such regulation. For these reasons, EPA's final "regulatory classification" of ETS as a Group A carcinogen is clearly beyond EPA's statutory authority.

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- C. EPA has failed to organize and utilize the committees required by Congress in the Radon Act.

III. EPA's Classification of ETS as a Group A Carcinogen Is Arbitrary and Capricious.

- A. EPA deviated from accepted scientific principles of chemistry, epidemiology and toxicology, as well as its own publicly announced guidelines for conducting cancer risk assessments. EPA manipulated and "cherry-picked" scientific data, ignored recent but contrary studies, and employed scientific assumptions and methodologies not accepted by the scientific community or even by the EPA itself in other contexts.
- B. The epidemiologic data relied upon by EPA are not sufficient to support a finding that ETS causes cancer. Neither the individual published studies nor EPA's meta-analysis satisfies the basic criteria, set forth in EPA's own guidelines, for determining whether ETS is a human carcinogen.
- C. EPA "reanalyzed" many of the epidemiological studies in an attempt to make otherwise nonstatistically significant study results appear statistically significant.

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- D. Of the eleven epidemiological studies conducted in the United States, to which EPA attached special importance, none is significant as originally reported, and only one appears statistically significant as reanalyzed,.
- E. The scientific literature identifies as potential confounding factors: diet, lifestyle choices, occupational factors, and environmental factors. Some of these potential confounders are of such magnitude as to account completely for any statistical association between ETS and lung cancer. EPA acknowledged the existence of confounding factors, but ignored its own Risk Assessment Guidelines' requirement to rule out such factors before claiming that ETS causes lung cancer.
- F. Recognizing that analysis of the individual epidemiologic studies could not support a Group A classification, EPA pooled, or "meta-analyzed," select portions of the epidemiological data in a manner that violates accepted scientific methodology.
- G. EPA also attempted to support its decision to classify ETS as a Group A carcinogen on an independent ground: analysis of a "proxy" substance: mainstream smoke. In so doing, EPA ignored the well-established fact that ETS and MS are not equivalent substances.

- H. The multiple and demonstrative differences between ETS and MS preclude any rational analysis of ETS using data on mainstream smoke. This is well recognized by the public health community. The Surgeon General concluded in 1986 that knowledge of MS chemical composition is of limited assistance in evaluating ETS: "Comparison of the relative concentrations of various components of SS and MS smoke provides limited insights concerning the toxicological potential of ETS in comparison with active smoking."
- I. Similarly, in 1986 the National Research Council concluded that data on MS do not provide a basis for predicting ETS exposure effects: "Because the physicochemical nature of ETS, MS, and SS differ, the extrapolation of health effects from studies of MS or of active smokers to nonsmokers exposed to ETS may not be appropriate ..."

IV. EPA Failed to Follow Its Own Publicly Announced Guidelines.

- A. Contrary to EPA's Exposure Assessment Guidelines, the ETS risk assessment is not based on accurate or verifiable information concerning actual exposure to ETS.
- B. EPA violated its own Risk Assessment Guidelines by failing to rule out the possibility that any association between ETS and lung

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cancer is attributable to chance, confounders, or bias, and by failing to consider the absence of a strong statistical association or a dose-response relationship.

- C. EPA also violated its own guidelines because it: (1) did not follow accepted statistical principles; (2) engaged in unjustified biological assumptions; (3) failed to give full consideration to "all relevant scientific information;" (4) failed to "fully present" critical scientific information; (5) failed to "use the most scientifically appropriate interpretation to assess risk;" and (6) failed to acknowledge and describe uncertainties, assumptions and limitations in both the data and its interpretation.

V. EPA's Actions in Failing to Comply with Statutory Requirements and Restrictions, Required Procedures and EPA's Own Guidelines Violated Plaintiffs' Right to Due Process of Law.

VI. Classification of ETS as a Group A Carcinogen Constitutes Final Agency Action, and Therefore Can Be Challenged in Court Under the Administrative Procedures Act (APA).

- A. EPA expected and intended its action to have a substantial regulatory impact, by restricting smoking in the workplace and in public. In this regard, former EPA Administrator William Reilly

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stated that EPA was seeking to bring about private lawsuits to drive the enforcement of EPA's decisions.

- B. Private entities fearing liability have been compelled, by the Risk Assessment, to institute restrictions or total bans on smoking in their buildings. Such actions were taken in express reliance, on the presumed soundness of the science underlying EPA's decision.

VII. Plaintiffs and the Public Have Been Injured by EPA's Action.

- A. The public is harmed any time the EPA engages in what EPA's Expert Panel characterized as the uneven and haphazard interpretation and use of science.
- B. Private entities and governments throughout the country have already undertaken action or are actively considering taking action to restrict smoking, as a direct result of EPA's Risk Assessment on ETS. EPA's Regulatory Program on ETS has adversely impacted and injured plaintiffs.
- C. The actions to restrict indoor smoking are based upon the presumed reliability of the EPA's "regulatory program" and pronouncements on ETS.